



MAY - 6 2002

Mr. Robert Doster
Senior Vice President of Scientific Affairs
Enzymatic Therapy, Inc.
825 Challenger Drive
Green Bay, Wisconsin 54311

Dear Mr. Doster:

This is in response to your letters of April 16, 17, 18, 23, and 24, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Enzymatic Therapy, Inc. is making the claims identified below, among others, for the product **Petadolex Patented Brain Support®**.

The product **Petadolex Patented Brain Support®** uses the claims "Normal Blood vessel tone in the brain is characterized by lack of headache, lack of auras, lack of nausea or vomiting, and lack of sensitivity to light and sound," "Healthy brain function is characterized by lack of headache, lack of auras, lack of nausea or vomiting, and lack of sensitivity to light and sound; Promotes Leg Vein Health," "...supports healthy blood vessel tone and normal blood flow in the brain," and "In a recent placebo-controlled clinical study participants reported a 62% improvement." These claims are disease claims because they suggest that the product is intended to treat, prevent, or mitigate diseases, namely disorders of blood flow and blood vessel tone in the brain that result in characteristic signs or symptoms of diseases such as headache, auras, nausea or vomiting, and sensitivity to light and sound. In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1015-17), FDA stated that claim to affect characteristic signs or symptoms of a disease or class of diseases are disease claims. We stated that a reference to a physiological sign or symptom is an implied disease claim if the condition to be treated or prevented is a disease and the signs and symptoms referred to in the labeling, in context, are characteristic of a disease or class of diseases and thus create an inference that the product is intended to treat or prevent the disease (65 FR at 1017). The states identified in your claim (i.e., headache, auras, nausea or vomiting, and sensitivity to light and sound) are not normal states of the brain. Alone or in combination, however, they are characteristic signs or symptoms of diseases, for example, migraine headaches and epilepsy. Therefore, in the context of the claims for your product that it "supports healthy blood vessel tone and normal blood flow in the

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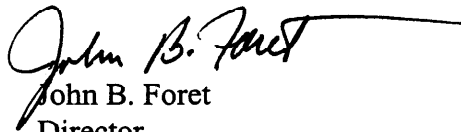
LET 602

brain” and has been shown result in “62% improvement” the statements about the product promoting blood flow and blood vessel tone and preventing headache, auras, nausea or vomiting, and sensitivity to light and sound clearly evidence that the product is intended to treat consequences of abnormal conditions of brain blood vessel tone and circulation that are diseases.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggests that it is intended to treat, prevent, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA’s Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,



John B. Foret
Director

Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Minnesota District Office, Office of Compliance, HFR-MW240

EnzymaticTherapy®

NATURAL MEDICINES™

April 17, 2002

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
U. S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

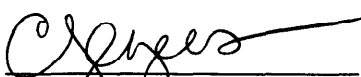
RE: Label Claims/Disclaimers

Dear Sir/Madam:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a manufacturer and has included statements provided for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product.

<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Petadolex®	Purple Butterbur (Petasites hybridus) Root Extract	Neurologist recommended Petadolex contains patented extract of butterbur that supports healthy blood vessel tone and normal blood flow in the brain.*

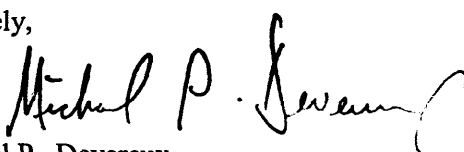
I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 
Cheryl Myers
Title: Director of Product Development

Date: 4-17-02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,


Michael P. Devereux
Chief Financial Officer
Petadolex 2e

EnzymaticTherapy®

NATURAL MEDICINES™

April 16, 2002

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
U. S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

RE: Label Claims/Disclaimers

Dear Sir/Madam:

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<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Petadolex®	Purple Butterbur (Petasites hybridus) Root Extract	Patented Brain Support*

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

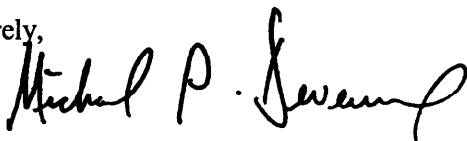
By: 
Cheryl Myers

Title: Director of Product Development

Date: 4-16-02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux
Chief Financial Officer

Petadolex 1c

825 Challenger Drive

Green Bay, WI 54311-8328

Ph: 920-469-1313

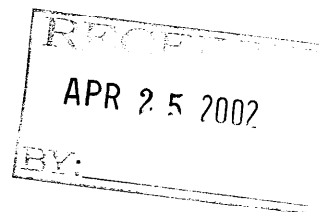
Fax: 888-570-6460

www.enzy.com

EnzymaticTherapy®
NATURAL MEDICINES™

April 24, 2002

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
U. S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835



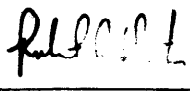
RE: Label Claims/Disclaimers

Dear Sir/Madam:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a manufacturer and has included statements provided for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product.

<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Petadolex® Patented Brain Support*	Purple Butterbur (Petasites hybridus) Root Extract	Healthy brain function is characterized by lack of headache, lack of auras, lack of nausea or vomiting, and lack of sensitivity to light and sound.*

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

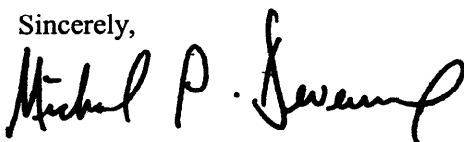
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4-24-02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux
Chief Financial Officer

Petadolex Patented Brain Support 4c

EnzymaticTherapy®
NATURAL MEDICINES™

April 23, 2002

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
U. S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

RE: Label Claims/Disclaimers

Dear Sir/Madam:

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<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Petadolex® Patented Brain Support*	Purple Butterbur (Petasites hybridus) Root Extract	Normal blood vessel tone in the brain is characterized by lack of headache, lack of auras, lack of nausea or vomiting, and lack of sensitivity to light and sound.*

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4-23-02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux

Michael P. Devereux
Chief Financial Officer

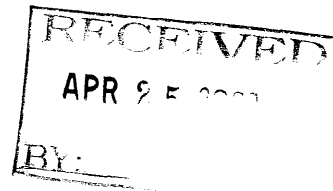
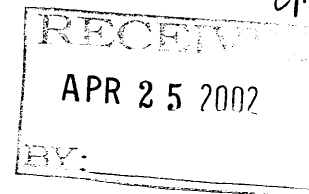
Petadolex Patented Brain Support 4e

825 Challenger Drive
Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com



EnzymaticTherapy®

NATURAL MEDICINES™

April 18, 2002

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
U. S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

RE: Label Claims/Disclaimers

Dear Sir/Madam:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a manufacturer and has included statements provided for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product.

<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Petadolex®	Purple Butterbur (Petasites hybridus) Root Extract	In a recent placebo- controlled clinical study participants reported a 62% improvement.*

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

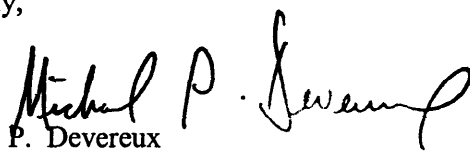
By: 
Cheryl Myers

Title: Director of Product Development

Date: 4-18-02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,


Michael P. Devereux
Chief Financial Officer

Petadolex 3c